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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------------|
| 10/582,671 | 06/12/2006 | Walther Jary | 4662-193 | 5006 |
| 23117 7590 06/20/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | EXAMINER ZUCKER, PAUL A | |
| | | | ART UNIT 1621 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/582,671 | JARY ET AL. | |
| | Examiner | Art Unit | |
| | Paul A. Zucker | 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-10 and 12-19 is/are rejected.
- 7) ☒ Claim(s) 5, 6 and 11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/12/32006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claim 19 is rejected under 35 U.S.C. 101 because it is drawn to non-statutory matter. The claimed recitation of a process, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "allylamine" in line 3. The structures (I) referred to, however, are *homoallyl*amines not allylamines. The intended scope of Applicants' claim is therefore unclear. Claim 1 and its dependents are therefore rendered indefinite.
2. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 19 is drawn to the use of products as produced in claim 1 as pharmaceutical intermediates, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 19 is therefore rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 8, 9 and 13- 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Boesten et al (US 2003/0097005 05-2003). Boesten discloses (Paragraphs [0083]-[0088]) the ozonolysis of (R)-phenylglycine Amide-(R)-isopropylhomoallylamine. The reaction is either carried out under oxidative (NaOH/MeOH) conditions (with autogenous oxygen or ozonide at room temperature (25°C)) to give the methyl ester or followed by reduction to the alcohol with and then a water quench using at least 1-2 equivalents based on NaBH₄ followed by aqueous extraction and chromatography. Boesten therefore anticipates claims 1-3, 8, 9 and 13- 17.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-4, 7-10 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boesten et al (US 2003/0097005 05-2003) in view of Bailey (Chemical Reviews, The Reactions of Ozone with Organic Compounds, 1958, 58(5), pages 925-1010).

Instantly claimed is a process for the successive ozonolysis of compounds of formula (I) followed by either reduction or oxidation.

Boesten teaches (Paragraphs [0083]-[0088]) the ozonolysis of (R)-phenylglycine Amide-(R)-isopropylhomoallylamine. The reaction is either carried out under oxidative (NaOH/MeOH) conditions (with autogenous oxygen or ozonide at room temperature (25°C)) to give the methyl ester or followed by reduction to the alcohol with and then a water quench using at least 1-2 equivalents based on NaBH₄ followed by aqueous extraction and chromatography.

The differences between the processes taught by Boesten and those instantly claimed are that:

- a. Boesten teaches reaction at -78°C while temperatures of reaction between -40°C to $+30^{\circ}\text{C}$ are instantly claimed;
- b. Boesten teaches oxidation to form the ester while oxidation to form the acid is instantly claimed; and,
- c. Boesten teaches only reduction with NaBH_4 to form the alcohol while reduction with agents such as hydrogen/catalyst combinations are instantly claimed.

Bailey teaches (Page 986, 1st 3 paragraphs) the use of a variety of solvents including acetic acid at temperatures of between -25°C to $+25^{\circ}\text{C}$. Bailey teaches (Page 989, Table 7) the oxidation of a large variety of substrates to the carboxylic acid in the presence of oxidizing agents such as O_2 or H_2O_2 . Baily teaches (Page 991, Table 8, entries 1 and 4) the catalytic reduction to produce aldehydes.

Thus one of ordinary skill in the art would have been motivated to modify the processes of Boesten according to the teachings of Bailey in order to extend the utility of Boesten's processes to other product classes and optimize yields. There would have been a reasonable expectation for success based upon the generality of Bailey's teaching.

Claim Objections

5. Claims 5, 6 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. Claim 19 is objected to because of the following informalities: The word "acides" in line 1 is misspelled. Appropriate correction is required.

Allowable Subject Matter

7. Claims 5, 6 and 11 are drawn to allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: The prior art neither teaches nor fairly suggests the instantly claimed combination of solvent ratios, temperatures and other reaction conditions.

Conclusion

8. Claims 1-18 are pending. Claims 1-4, 7-10 and 12-19 are rejected. Claims 5, 6 and 11 are objected to.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter R. Johann can be reached on 571-272-0646. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Paul A. Zucker
Primary Examiner
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